#### NOTICES OF EXEMPT RULEMAKING

The Administrative Procedure Act requires the *Register* publication of the rules adopted by the state's agencies under an exemption from all or part of the Administrative Procedure Act. Some of these rules are exempted by A.R.S. §§ 41-1005 or 41-1057; other rules are exempted by other statutes; rules of the Corporation Commission are exempt from Attorney General review pursuant to a court decision as determined by the Corporation Commission.

#### NOTICE OF EXEMPT RULEMAKING

#### TITLE 6. ECONOMIC SECURITY

# CHAPTER 5. DEPARTMENT OF ECONOMIC SECURITY SOCIAL SERVICES

#### **PREAMBLE**

#### 1. Sections Affected

### Rulemaking Action

Appendix B Amend

### 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statute the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 41-1005(A)(26), 41-1954(A)(3), 46-134(A)(12), 46-805

Implementing statutes: A.R.S. §§ 46-801 through 46-810 Statute authorizing the exemption: A.R.S. § 41-1005(A)(26)

#### 3. The effective date of the rules:

The effective date is October 1, 2001. This date is consistent with statutory and appropriations requirements regarding eligibility levels and reimbursement rates.

#### 4. A list of all previous notices appearing in the Register addressing the exempt rule:

None

#### 5. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Beth A. Broeker

Address: Department of Economic Security

1798 W. Jefferson, Site Code 837A

Phoenix, AZ 85007

or

Department of Economic Security P.O. Box 6123, Site Code 837A

Phoenix, AZ 85005

Telephone: (602) 542-6555 Fax: (602) 542-6000

E-mail: bbroeker@mail.de.state.az.us

### 6. An explanation of the rule, including the agency's reason for initiating the rule, including the statutory citation to the exemption from the regular rulemaking procedures:

A.R.S. § 41-1005(A)(26) gives the Department an exemption from the Administrative Procedure Act to develop rules under A.R.S. § 46-805. This statute gives the Department the authority to establish payment rates for child care assistance. The Department is adopting new Maximum Reimbursement Rates For Child Care to establish maximum provider reimbursement rates the Department will pay for child care subsidies when services are provided by Department of Health Services licensed child care centers, Department of Health Services certified child care group homes and Department of Economic Security certified family homes and certified in-home providers.

#### **Notices of Exempt Rulemaking**

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of the state:

Not applicable

9. The summary of the economic, small business, and consumer impact:

Because these rules are exempt from the Administrative Procedure Act under A.R.S. § 41-1005(A)(26), the Department did not prepare an economic impact statement.

10. A description of the changes between the proposed rule, including supplemental notices, and final rules (if applicable):

Not applicable

11. A summary of the principle comments and the agency response to them:

Not applicable

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporations by reference and their location in the rules:

Not applicable

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

#### TITLE 6. ECONOMIC SECURITY

# CHAPTER 5. DEPARTMENT OF ECONOMIC SECURITY SOCIAL SERVICES

ARTICLE 49. CHILD CARE ASSISTANCE

Section

Appendix B. Maximum Reimbursement Rates For Child Care

ARTICLE 49. CHILD CARE ASSISTANCE

Appendix B. Maximum Reimbursement Rates For Child Care

ARIZONA DEPARTMENT OF ECONOMIC SECURITY
DIVISION OF EMPLOYMENT & REHABILITATION SERVICES
CHILD CARE ADMINISTRATION

**MAXIMUM REIMBURSEMENT RATES FOR CHILD CARE** 

(effective for services provided on or after 7/1/99)

**CENTERS** 

Age Group	<del>District I</del>	District II	District III	District IV	District V	District VI
Birth < 1 yr:						
<del>Full day</del>	<del>25.20</del>	<del>22.00</del>	<del>18.80</del>	<del>21.00</del>	<del>15.00</del>	<del>16.47</del>
<del>Part day</del>	<del>18.80</del>	<del>16.20</del>	<del>16.00</del>	<del>12.00</del>	<del>12.00</del>	<del>10.60</del>
1 yr < 3 yrs:						
Full day	<del>22.00</del>	<del>20.93</del>	<del>17.21</del>	<del>16.00</del>	<del>20.50</del>	<del>16.47</del>
Part day	<del>15.40</del>	<del>14.00</del>	<del>14.00</del>	<del>12.00</del>	<del>12.00</del>	<del>12.00</del>
3 yrs < 6 yrs:						
Full day	<del>20.00</del>	<del>18.72</del>	<del>16.74</del>	<del>16.00</del>	<del>16.67</del>	<del>16.47</del>
<del>Part day</del>	<del>14.00</del>	<del>13.00</del>	<del>13.00</del>	<del>11.60</del>	<del>12.40</del>	<del>10.40</del>
6 yrs < 13 yrs:						
<del>Full day</del>	<del>20.00</del>	<del>19.00</del>	<del>16.80</del>	<del>16.28</del>	<del>16.00</del>	<del>14.00</del>
Part day	<del>12.00</del>	<del>11.50</del>	12.00 PHOMES	<del>11.00</del>	<del>13.33</del>	<del>11.00</del>

Age Group	<del>District I</del>	District II	District III	District IV	<del>District V</del>	District VI
Birth < 1 yr:						
Full day	<del>19.00</del>	<del>16.00</del>	<del>17.50</del>	<del>15.00</del>	<del>15.00</del>	<del>17.00</del>
Part day	12.00	<del>14.00</del>	<del>12.00</del>	9.00	<del>7.50</del>	14.00
1 yr < 3 yrs:						
Full day	<del>18.00</del>	<del>16.00</del>	<del>15.00</del>	<del>15.00</del>	<del>15.00</del>	<del>15.00</del>
Part day	<del>12.00</del>	<del>12.00</del>	<del>12.00</del>	9.00	<del>7.50</del>	14.00
3 yrs < 6 yrs:						
Full day	<del>17.00</del>	<del>16.00</del>	<del>15.00</del>	<del>13.95</del>	<del>15.00</del>	<del>15.00</del>
Part day	<del>12.00</del>	<del>12.00</del>	<del>11.63</del>	8.00	<del>7.50</del>	14.00
6 yrs < 13 yrs:						
Full day	<del>17.00</del>	<del>16.00</del>	<del>15.00</del>	<del>13.00</del>	<del>15.00</del>	<del>15.00</del>
Part day	<del>12.00</del>	<del>11.00</del>	<del>11.63</del>	<del>7.60</del>	<del>7.50</del>	14.00

#### **CERTIFIED FAMILY HOMES & CERTIFIED IN-HOME PROVIDERS**

Age Group	District I	<del>District II</del>	<del>District III</del>	District IV	<del>District V</del>	District VI
Birth < 1 yr:						
<del>Full day</del>	<del>18.00</del>	<del>16.00</del>	<del>16.00</del>	<del>15.00</del>	<del>16.00</del>	<del>15.00</del>
Part day	<del>12.00</del>	<del>10.00</del>	<del>8.00</del>	<del>8.00</del>	8.00	8.00
1 yr < 3 yrs:						
<del>Full day</del>	<del>17.00</del>	<del>15.00</del>	<del>16.00</del>	<del>15.00</del>	<del>15.00</del>	<del>15.00</del>
Part day	<del>11.00</del>	<del>10.00</del>	<del>8.00</del>	<del>8.00</del>	<del>8.00</del>	8.00
3 yrs < 6 yrs:						
<del>Full day</del>	<del>16.00</del>	<del>15.00</del>	<del>15.00</del>	<del>13.00</del>	<del>15.00</del>	<del>15.00</del>
Part day	10.00	<del>9.00</del>	<del>8.00</del>	<del>8.00</del>	<del>8.00</del>	<del>8.00</del>
6 yrs < 13 yrs:						
<del>Full day</del>	<del>16.00</del>	<del>15.00</del>	<del>15.00</del>	<del>13.00</del>	<del>15.00</del>	<del>15.00</del>
Part day	10.00	<del>9.00</del>	<del>8.00</del>	<del>7.50</del>	<del>8.00</del>	<del>8.00</del>

Full day =  $\sin$  or more hours per day

Part day = less than six hours per day

The maximum reimbursement rates may be increased by up to ten percent, for child care providers who are nationally accredited.

Actual reimbursement will be provider's actual charges, minus any client designated co-pay, not to exceed maximum reimbursement rates.

# ARIZONA DEPARTMENT OF ECONOMIC SECURITY DIVISION OF EMPLOYMENT & REHABILITATION SERVICES CHILD CARE ADMINISTRATION

#### MAXIMUM REIMBURSEMENT RATES FOR CHILD CARE

(effective for services provided on or after 10/1/2001)

#### **CENTERS**

Age Group	District I	<u>District II</u>	<u>District III</u>	District IV	District V	<u>District VI</u>
Birth $< 1 \text{ yr:}$						
Full day	<u>29.00</u>	<u>27.00</u>	<u>22.40</u>	<u>21.00</u>	<u>25.00</u>	<u>21.20</u>
Part day	<u>22.00</u>	<u>19.00</u>	<u>16.00</u>	<u>19.00</u>	<u>25.00</u>	<u>13.00</u>
1  yr < 3  yrs:						
Full day	<u>25.58</u>	<u>24.00</u>	<u>20.00</u>	<u>18.25</u>	<u>25.00</u>	<u>20.80</u>
Part day	<u>19.00</u>	<u>18.00</u>	<u>15.00</u>	<u>16.00</u>	<u>15.00</u>	<u>13.80</u>
3 yrs < 6 yrs:						
Full day	<u>23.20</u>	<u>22.00</u>	<u>18.00</u>	<u>17.00</u>	<u>20.00</u>	<u>17.60</u>
Part day	<u>16.00</u>	<u>15.40</u>	<u>13.02</u>	<u>15.50</u>	<u>12.40</u>	<u>12.20</u>
<u>6 yrs &lt; 13 yrs:</u>						
Full day	<u>22.00</u>	<u>21.20</u>	<u>16.80</u>	<u>17.00</u>	<u>20.00</u>	<u>18.90</u>
Part day	<u>15.00</u>	<u>13.60</u>	<u>12.00</u>	14.00	<u>13.33</u>	<u>12.00</u>

#### **GROUP HOMES**

Age Group	District I	District II	District III	District IV	District V	District VI
Birth < 1 yr:						
Full day	20.00	20.00	<u>18.00</u>	<u>18.00</u>	<u>18.00</u>	<u>18.00</u>
Part day	<u>14.00</u>	14.00	<u>15.00</u>	<u>12.00</u>	<u>12.00</u>	<u>14.00</u>
1 yr < 3 yrs:						
Full day	20.00	20.00	<u>18.00</u>	<u>17.50</u>	<u>18.00</u>	<u>18.00</u>
Part day	14.00	<u>15.00</u>	<u>13.00</u>	<u>12.00</u>	<u>11.00</u>	<u>14.00</u>
3 yrs < 6 yrs:						
Full day	20.00	20.00	<u>18.00</u>	<u>16.00</u>	<u>18.00</u>	<u>16.00</u>
Part day	<u>13.00</u>	<u>15.00</u>	<u>12.00</u>	<u>12.00</u>	<u>10.00</u>	<u>14.00</u>
6 yrs < 13 yrs:						
Full day	<u>17.00</u>	20.00	16.00	<u>16.00</u>	<u>18.00</u>	<u>16.00</u>
Part day	12.00	<u>13.00</u>	<u>12.00</u>	<u>11.00</u>	<u>10.00</u>	<u>14.00</u>

#### CERTIFIED FAMILY HOMES & CERTIFIED IN-HOME PROVIDERS

Age Group	District I	District II	District III	District IV	District V	District VI
Birth < 1 yr:						
Full day	20.00	<u>17.00</u>	<u>17.00</u>	<u>16.00</u>	<u>17.00</u>	<u>16.00</u>
Part day	<u>12.00</u>	<u>10.00</u>	<u>10.00</u>	<u>8.50</u>	<u>10.00</u>	<u>8.00</u>
1  yr < 3  yrs:						
Full day	<u>18.00</u>	<u>17.00</u>	<u>16.00</u>	<u>15.00</u>	<u>16.00</u>	<u>16.00</u>
Part day	<u>12.00</u>	<u>10.00</u>	<u>10.00</u>	<u>8.00</u>	<u>10.00</u>	<u>8.00</u>
3 yrs < 6 yrs:						
Full day	<u>17.00</u>	<u>16.00</u>	<u>16.00</u>	<u>15.00</u>	<u>16.00</u>	<u>15.00</u>
Part day	<u>12.00</u>	<u>10.00</u>	<u>10.00</u>	<u>8.00</u>	<u>9.00</u>	<u>8.00</u>
6 yrs < 13 yrs:						
Full day	<u>16.00</u>	<u>16.00</u>	<u>16.00</u>	<u>15.00</u>	<u>15.00</u>	<u>15.00</u>
Part day	<u>10.00</u>	<u>10.00</u>	9.00	8.00	9.00	8.00

Full day =  $\sin$  or more hours per day

Part day = less than six hours per day

The maximum reimbursement rates may be increased by up to ten percent, for child care providers who are nationally accredited.

Actual reimbursement will be provider's actual charges, minus any client designated co-pay, not to exceed maximum reimbursement rates.

#### NOTICE OF EXEMPT RULEMAKING

#### TITLE 9. HEALTH SERVICES

# CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

#### **PREAMBLE**

<u>1.</u>	Sections Affected	Rulemaking Action
	R9-25-101	Amend
	R9-25-206	Amend
	R9-25-514	Amend
	R9-25-615	Amend
	R9-25-803	Amend
	R9-25-804	New Section

### 2. The specific authority for rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-136(F), 36-2202(A), 36-2205(C), and 36-2209(A)

Implementing statutes: A.R.S. §§ 36-2205 and 36-2232

#### 3. The effective date of the rule:

November 1, 2001

#### 4. A list of all previous notices appearing in the Register addressing the exempt rule:

None

#### 5. The name and address of agency personnel by whom persons may communicate regarding the rulemaking:

Name: Kathleen Phillips, Rules Administrator

Address: Department of Health Services

1740 W. Adams Street Phoenix, AZ 85007

Telephone: (602) 542-1264 Fax: (602) 364-1150

or

Name: Judi Crume, Bureau Chief

Address: Department of Health Services, Bureau of Emergency Medical Services

1651 E. Morten, Suite 120

Phoenix, AZ 85020

Telephone: (602) 861-0708 Fax: (602) 861-9812

### 6. An explanation of the rule, including the agency's reason for initiating the rule, including the statutory citation to the exemption from the regular rulemaking procedures:

During the 45th regular legislative session, A.R.S. §§ 36-2205 and 36-2232 were amended through SB1319 to require the Department to establish protocols for emergency medical providers and ambulance services to refer, advise, or transport emergency medical patients, whose conditions do not pose an immediate threat to life or limb,

#### **Notices of Exempt Rulemaking**

by the most appropriate means to the most appropriate health care institution based upon a patient's condition. SB1319 was signed by the Governor on April 19, 2001 and became effective on August 10, 2001.

9 A.A.C. 25 currently limits emergency medical patient transport by emergency medical providers and ambulance services to emergency receiving facilities. An emergency receiving facility is defined in A.R.S. § 36-2201(17) as a licensed health care institution that offers emergency medical services, is staffed 24 hours a day, and has a physician on call.

This rulemaking amends R9-25-101, R9-25-206, R9-25-514, R9-25-615, and R9-25-803 to add or amend definitions and to replace references to emergency receiving facilities with references to health care institutions. This amendment allows the emergency medical technician's medical director, through communication with the emergency medical technician or through Department approved emergency medical treatment and triage protocols, to determine which health care institution is appropriate given the circumstances of the emergency medical patient.

A new rule, R9-25-804, is added to specify the conditions under which an emergency medical patient may be transported to a health care institution other than an emergency receiving facility, and establishes minimal reporting requirements for emergency medical services providers and ambulance services.

The Department worked with representatives from medical facilities, hospitals, fire departments, ambulance services, academia, the public, and the Department's two citizen advisory groups, the Emergency Medical Services Council and the Medical Direction Commission on this rulemaking. The rules have been accepted by the Medical Director of the Bureau of Emergency Medical Services.

This rulemaking is made under an exemption from A.R.S. Title 41, Chapter 6 authorized by Laws 2001, Chapter 157. Session Law in SB1319 grants the Department an exemption from the rulemaking requirements in A.R.S. Title 41, Chapter 6 for the purpose of adopting new rules and revising existing rules, authorized under A.R.S. §§ 36-2202, 36-2205, and 36-2232, necessary to implement the statutory amendment.

7. A reference to any study that the agency relied on in its evaluation of or justification for the rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:

Not applicable

8. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

9. The summary of the economic, small business and consumer impact:

Session Law in SB1319, Laws 2001, Chapter 157, provides exemption from the provisions of Title 41, Chapter 6.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Not applicable

11. A summary of the principal comments and the agency response to them:

Not applicable

12. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

13. Incorporation by reference and their location in the rules:

None

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rule follows:

#### TITLE 9. HEALTH SERVICES

# CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

#### **ARTICLE 1. DEFINITIONS**

Section

R9-25-101. Definitions. (Authorized by A.R.S. §§ 36-2202(A), (2), (3), (4), and 36-2204(1)-(7))

#### ARTICLE 2. ADVANCED LIFE SUPPORT BASE HOSPITAL CERTIFICATION

Section

R9-25-206. Base Hospital Authority and Responsibilities. (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), and 36-2204(5) and (6))

#### ARTICLE 5. BASIC LIFE SUPPORT CERTIFICATION

Section

R9-25-514. Reporting Requirements. (Authorized by A.R.S. §§ 36-2202(A)(2), (3), and (4), and 36-2204(1) and (6))

#### ARTICLE 6. ADVANCED LIFE SUPPORT CERTIFICATION

Section

R9-25-615. Reporting Requirements. (Authorized by A.R.S. §§ 36-2202(A)(2), (3), and (4), and 36-2204(1) and (6))

#### ARTICLE 8. MEDICAL DIRECTION PROTOCOL FOR EMERGENCY MEDICAL TECHNICIANS

Section

R9-25-803. Protocol for Drug Box Procedures

R9-25-804. Reserved Protocol for Selection of a Health Care Institution for Emergency Medical Patient Transport

#### ARTICLE 1. DEFINITIONS

#### R9-25-101. Definitions (Authorized by A.R.S. § 36-2202(A), (2), (3), (4), and 36-2204(1)-(7))

In Articles 2 through 6 8 of this Chapter, unless the context otherwise requires:

- 1. No change
- 2. No change
- 3. "Administrative medical direction for ALS personnel" means supervision of prehospital providers by the base hospital medical director has the same meaning as A.R.S. § 36-2201.
- 4. "Administrative medical direction for EMT-Basic" means supervision of EMT-Basic prehospital providers by a base hospital medical director or basic life support medical director.
- 5.4. "Advanced cardiac life support" or "ACLS" means invasive, pharmacologic, or mechanical electrical cardiovascular care
- 6.5. "Advanced cardiac life support instructor" or "ACLS instructor" means an individual who has successfully completed an American Heart Association Advanced Cardiac Life Support Instructor Course and holds a current instructor's card.
- 7.6. "Advanced cardiac life support provider" or "ACLS provider" means an individual who has successfully completed an advanced cardiac life support provider course and has demonstrated competency in rhythm interpretation, advanced airway management, peripheral and central intravenous lines, and pharmacologic and mechanical electrical dysrhythmia therapy.
- 8.7. "Advanced life support" or "ALS" means those medical treatments, procedures, including assessment, and techniques which may be administered or performed by ALS personnel established pursuant to A.R.S. § 36-2205.
- 9.8. "Agency" means an organization that provides prehospital emergency medical services.
- 10.9. "ALS personnel" means a paramedic or an intermediate certified under Article 6 of this Chapter.
- 11.10. "Basic cardiac life support" or "BCLS" means non-invasive external cardiovascular care.
- 12.11. "Basic cardiac life support instructor" or "BCLS instructor" means an individual who has successfully completed a basic cardiac life support instructor course and holds a current instructor's card issued by the American Heart Association, American Red Cross, Red Cresent Association of Canada, National Safety Council, Medic First Aid, or the Save-a-Life Foundation of Tucson, Arizona.
- 13.12. "Basic life support" or "BLS" means those medical treatments, procedures, and techniques which may be administered or performed by emergency medical technicians.

#### **Notices of Exempt Rulemaking**

- 14. "Basic life support medical director" means a physician licensed pursuant to A.R.S. Title 32, Chapter 13 or 17, in good standing, who provides administrative medical direction to basic emergency medical technicians.
- 15.13. "Challenge course" means a course that prepares and enables specified individuals to apply for and take certification exams in Arizona without repeating an entire training course.
- 16.14. "Clinical" means providing direct patient care.
- 17.15. "Competency" means ability to perform a skill to the standard of care.
- 18:16. "Communication protocols" means written guidelines that provide:
  - a. No change
  - b. No change
  - c. No change
- 19.17. "Conference/Didactic/Lecture session" means a continuing medical education presentation by an individual or a presentation utilizing printed, electronic, or audiovisual media that incorporates a post training assessment.
- 20.18. "Continuing education" means a planned, organized learning experience designed to build upon the educational and experiential bases to enhance practice, education, administration, or research to improve health care to the public.
- 21.19. "Current status" means successful completion of a course in advanced cardiac life support or basic cardiac life support training every two years.
- 22.20. "Department" means the Department of Health Services.
- 23-21. "Designed to exclude bias" means a process that prevents discrimination against individuals based on age, race, religion, sex, ethnic or national origin, or disability.
- 24.22. "Direct communications" means information and medical direction conveyed by person-to-person, 2-way radio, or telephone conversation.
- 25.23. "Distractors" means incorrect answers incorporated into multiple choice test design.
- 26.24. "Documented" means a written record.
- 27 25. "Emergency medical patient" means an individual who may require immediate prehospital assessment, treatment, transportation, or evaluation by a physician.
- 28.26. "Emergency medical service patient contacts" means patients received by a hospital health care institution from an EMS agency or patients on whom a field incident report form or first care form was initiated.
- 27. "Emergency medical services provider" has the same meaning as in A.R.S. § 36-2201 and includes an ambulance service.
- 28. "Emergency receiving facility" has the same meaning as in A.R.S. § 36-2201.
- 29. No change
- 30. No change
- 31. No change
- 32. No change
- 33. No change
- 34. No change
- 35. No change
- 36. "Health care institution" has the same meaning as in A.R.S. § 36-401.
- 36-37. "Health care provider" means an individual licensed or certified to render medical care to a patient.
- 37.38. "Indirect communications" means information and medical direction conveyed by an intermediary from within a certified ALS Base Hospital.
- 38.39. "Instructor intern" means an individual who assists an instructor in teaching in an EMT Training Program course and assumes, under direct supervision, the instructional and administrative functions of the course.
- 39.40. "Local EMS coordinating system" means an agency responsible for the coordination of a regional EMS system pursuant to A.R.S. § 36-2210.
- 41. "Medical direction" means providing emergency medical care instructions and guidance to an emergency medical technician through:
  - a. Voice communication conveyed by person-to-person, 2-way radio, or telephone; or
  - b. Treatment and triage protocols authorized under A.R.S. § 36-2205.
- 40.42. "Medical direction authorities" means a physician, nurse intermediary, physician's assistant, or nurse practitioner, who has attended the base hospital physician's orientation and is designated by the base hospital medical director to render on-line medical direction to prehospital EMS personnel from within a certified ALS Base Hospital.
- 43. "Medical director" means a physician currently licensed under A.R.S. Title 32, Chapter 13 or 17, and in good standing, who provides administrative medical direction or medical direction to an emergency medical technician.
- 41.44. "Multimedia instruction" means learning activities which have media-based format, computer-based format, or on-going serial productions, and which have an evaluative process that has been approved by the participant's medical direction authority.

- 42.45. "Official course end date" means the last scheduled day of classes as identified in the course schedule submitted to the Department pursuant to the requirements of Articles 3 or 4 of this Chapter.
- 43.46. "Official course roster" means a list of all students who successfully complete a training program course.
- 44.47. "Off-line medical direction" means development and approval, by the base hospital medical director, of written treatment protocols which comply with A.R.S. § 36-2205, that authorize prehospital providers to render patient care without on-line medical direction.
- 45.48. "On-line medical direction" means supervision of prehospital EMS personnel by medical direction authorities through direct or indirect communications from a certified ALS Base Hospital.
- 46.49. "Pediatric advanced life support provider" means an individual who has successfully completed a pediatric advanced life support provider course and has demonstrated competency in pediatric rhythm interpretation, advanced airway management, peripheral and central intravenous lines, intraosseous infusion, thoracostomy, and pharmacologic and electrical dysrhythmia therapy.
- 47.50. "Personal relationship" means a spouse, child, grandchild, parent, grandparent, brother, or sister of the whole or half blood and their spouse, and the parent, brother, or sister of the spouse.
- 48.51. "Predetermined medical direction" means development and approval of written protocols by a regional council developed in compliance with A.R.S. § 36-2205, including training and quality assurance components, and made available to the base hospitals.
- 49.52. "Prehospital case reviews" means continuing education conducted by the ALS Base Hospital under the direction of the base hospital medical director and ALS Base Hospital prehospital manager for the purpose of reviewing and evaluating patient care, and educational and administrative requirements of the prehospital providers assigned to the ALS Base Hospital.
- <del>50.53.</del> "Prehospital provider" means emergency medical technicians and individuals licensed or certified to render on-scene emergency medical care.
- 51.54. "Standing orders" means written orders which authorize prehospital personnel to render certain treatment modalities prior to initiation of direct communication with the ALS Base Hospital.
- 52.55. "Supervised clinical training" means documented experience of an EMT which details the EMT's in-hospital patient care performance supervised by a physician, emergency nurse, or another EMT at the same or higher level of certification.
- 53.56. "Supervised vehicular training" means documented experience of an EMT which details the EMT's prehospital patient care performance supervised by a vehicular preceptor.
- 54.57. "Tardiness" means arriving after the designated starting time.
- 58. "Transfer care" means to relinquish to the control of another the ongoing medical treatment of an emergency medical patient.
- 55 59. "Trauma patient management" means a competency based course in prehospital emergency care that includes training in prehospital emergency scene management, trauma patient assessment and treatment, triage standards, emergency transportation criteria, communication, documentation, mechanism of injury, trauma airway management, and shock resuscitation.
- 56.60. "Treatment protocols" means prehospital guidelines for utilizing treatments which are adopted pursuant to A.R.S. § 36-2205.
- 57.61. "Triage protocols" means prehospital guidelines for the selection of an emergency receiving facility a health care institution to which emergency patients are an emergency medical patient is transported.
- 58.62. "Vehicular preceptor" means a person acting as an agent of a base hospital or training program to observe, evaluate, supervise, or assist EMTs in the performance of skills during vehicular training.
- 59.63. "Vehicular preceptor experience" means observing, evaluating, supervising, or assisting EMTs in the performance of skills during vehicular training.
- 60.64. "Vehicular redealing experience" means experience on an emergency vehicle unit to gain prehospital experience and observe the prehospital environment, operational procedures, and performance of EMTs.
- 61.65. "Verification" or "verified statement" means a signed document that verifies the validity of statements or claims.

#### ARTICLE 2. ADVANCED LIFE SUPPORT BASE HOSPITAL CERTIFICATION

### R9-25-206. Base Hospital Authority and Responsibilities (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), and 36-2204(5) and (6))

- A. No change
- B. No change
- C. No change
- **D.** The base hospital and the agency shall jointly develop and implement:
  - 1. Written policies and procedures that all emergency medical technicians must follow. These policies and procedures shall include:
    - a. No change

- b. No change
- c. No change
- d No change
- e. A requirement for all prehospital medical personnel, operating under predetermined medical control and offline medical control, to notify the receiving facility health care institution before prior to arrival.
- 2. No change
- 3. No change
- 4. No change
- E. No change
- F. No change
- G. No change
- **H.** The base hospital shall establish the following communication procedures:
  - 1. Provisions to notify a receiving <u>facility health care institution</u> of an incoming patient if notification has been made to the base hospital rather than the receiving <u>facility health care institution</u>.
  - 2. No change
- I. No change
- **J.** No change

#### ARTICLE 5. BASIC LIFE SUPPORT CERTIFICATION

#### R9-25-514. Reporting Requirements (Authorized by A.R.S. § 36-2202(A)(2), (3), and (4), and 36-2204(1) and (6))

An EMT-Basic affiliated with an agency shall ensure that:

- 1. No change
- 2. No change
- 3. The original or a legible copy of this report is provided to the prehospital provider, or the nurse or physician at the receiving facility receiving health care institution accepting transfer of patient care, and the person providing the EMT-Basic's administrative medical direction.

#### ARTICLE 6. ADVANCED LIFE SUPPORT CERTIFICATION

R9-25-615. Reporting Requirements (Authorized by A.R.S. §§ 36-2202(A)(2), (3), and (4), and 36-2204(1) and (6)) A paramedic or intermediate affiliated with an agency shall ensure that:

- 1. No change
- 2. No change
- 3. The original or a legible copy of this report is provided to the prehospital provider, or the nurse or physician at the receiving facility receiving health care institution accepting transfer of patient care, and the person providing the paramedic or intermediate administrative medical direction.

#### ARTICLE 8. MEDICAL DIRECTION PROTOCOL FOR EMERGENCY MEDICAL TECHNICIANS

#### R9-25-803. Protocol for Drug Box Procedures

A. In addition to the definitions in R9-25-101, the following definitions apply in this protocol unless otherwise specified:

- 1. No change
- 2. No change
- 3. No change
- 4. No change
- 5. No change
- 6. No change7. No change
- 8. No change
- 9. "Emergency receiving facility" means the same as the definition in A.R.S. § 36-2201.
- 10-9. "EMT-B" means a basic emergency medical technician and is the same as the definition in A.R.S. § 36-2201.
- 41-10. "Independent supplier" means an entity permitted by the State Board of Pharmacy pursuant to A.R.S. § 32-1929 to sell or stock drugs.
- 12.11. "Interfacility transport" means a prearranged ambulance transport of an individual receiving medical care from one licensed accredited hospital or licensed accredited health care institution to another licensed accredited hospital or licensed accredited health care institution.
- 13.12. "License" means the written authorization issued by the Department under A.R.S. Title 36, Chapter 4.
- 14. "Medical direction" means guidance provided by a physician for medical care of an individual through on-line medical direction, off-line medical direction, or standing orders.
- 15.13. "Monitor" means:
  - a. No change

- b. No change
- 16.14. "Physician" means an individual licensed pursuant to A.R.S. §§ 32-1301 or 32-1701.
- 17.15. "Registered nurse" means an individual licensed pursuant to A.R.S. § 32-1601.
- **B.** Only an individual authorized under R9-25-608 (B) or a registered nurse may administer a drug under the medical direction of a medical direction authority.
  - 1. No change
  - 2. A copy of the first care form in subsection (B)(1) shall be delivered to the pharmacy of the base hospital or emergency receiving hospital health care institution within 72 hours after the order is issued.
- **C.** A base hospital, emergency receiving facility, health care institution, or independent supplier who elects to provide the drugs listed in Exhibit 1 to an agency shall establish a written agreement with the agency to document:
  - 1. Written policies established by the base hospital, emergency receiving facility, health care institution, or independent supplier addressing requirements for secured drug boxes, distribution of drugs, drug box recordkeeping, and reporting.
  - 2. An agency's responsibility to provide a base hospital, an emergency a receiving facility, health care institution, or an independent supplier with drug boxes that:
    - a. No change
    - b. No change
    - c. No change
    - d. No change
  - 3. No change
  - 4. An EMT-I, EMT-P, or a registered nurse shall:
    - a. Monitor the contents of a drug box for expired drugs, deteriorated drugs, damaged drug containers or labels, altered drug containers or labels, or missing drugs. If any of these conditions occur, the EMT-I, EMT-P, or registered nurse shall notify the supervisor of the EMT-I, EMT-P or the registered nurse, the base hospital, the emergency receiving facility health care institution's pharmacy, or the independent supplier and return the affected drugs to the base hospital, the emergency receiving facility's health care institution's pharmacy, or the independent supplier.
    - b. No change
    - c. No change
- **D.** Within 72 hours of the discovery of any conditions in subsection (C)(4)(a) for a controlled substance, a base hospital, an emergency a receiving facility, health care institution, or an independent supplier shall notify the Department by telephone or facsimile transmission specifying the date of discovery, type of controlled substance involved and type of exception. If the notification is by telephone, the base hospital, the emergency receiving facility health care institution, or the independent supplier shall send to the Department by certified mail the information contained in this Section.
- **E.** An agency shall exchange or resupply drugs only from a base hospital, an emergency <u>a</u> receiving <u>facility health care institution</u>, or an independent supplier with which the agency has a current written agreement for resupplying drugs:
  - 1. If an agency is obtaining drugs from a base hospital, an emergency a receiving facility, health care institution, or an independent supplier that mandates a drug box-for-box exchange, the agency shall obtain sufficient drug boxes to assure the agency's acquisition of a new drug box within 30 minutes of the return of a used drug box to the base hospital or the emergency receiving facility health care institution.
  - 2. If an agency is obtaining drugs from a base hospital, an emergency a receiving facility, health care institution, or an independent supplier that allows drug-for-drug exchange, the agency shall ensure that an EMT-I, EMT-P, or a registered nurse documents the exchange on a form that includes the name of the drug exchanged and the date and time of exchange.
- **F.** Except as provided in subsection (I), a base hospital's pharmacy, an emergency a receiving facility, health care institution, or an independent supplier shall provide the contents of a drug box in the supply ranges set forth in Exhibit 1.
- G. No change
- H. No change

### R9-25-804. Reserved Protocol for Selection of a Health Care Institution for Emergency Medical Patient Transport

- **A.** An emergency medical technician shall, except as provided in subsection (B), transport an emergency medical patient to an emergency receiving facility.
- **B.** Under A.R.S. §§ 36-2205(E) and 36-2232(F), an emergency medical technician who responds to an emergency medical patient who has accessed 9-1-1 or a similar public dispatch number may refer, advise, or transport the emergency medical patient to the most appropriate health care institution, if the emergency medical technician:
  - 1. Determines, based upon medical direction, that the emergency medical patient's condition does not pose an immediate threat to life or limb;
  - 2. Provides the emergency medical patient with a written list of health care institutions that are available to deliver emergency medical care to the emergency medical patient. The list shall:

- a. Include the name, address, and telephone number of each health care institution;
- b. If a health care institution is licensed under A.R.S. Title 36, Chapter 4, identify the classification or subclassification of the health care institution assigned under 9 A.A.C. 10; and
- c. Only include a health care institution that the medical director has determined is able to accept an emergency medical patient; and
- 3. Determines, based upon medical direction, the health care institution to which the emergency medical patient may be transported, based on the following:
  - a. The patient's:
    - i. Medical condition,
    - ii. Choice of health care institution, and
    - iii. Health care provider; and
  - b. The location of the health care institution and the emergency medical resources available at the health care institution.
- C. Before initiating transport of an emergency medical patient, an emergency medical technician, emergency medical services provider, or ambulance service shall notify, by radio or telephone communication, a health care institution that is not an emergency receiving facility of the emergency medical technician's intent to transport the emergency medical patient to the health care institution.
- **D.** An emergency medical technician transporting an emergency medical patient to a health care institution that is not an emergency receiving facility shall transfer care of the emergency medical patient to a designee authorized by:
  - 1. A physician licensed under A.R.S. Title 32, Chapter 13 or 17;
  - 2. A physician assistant licensed under A.R.S. Title 32, Chapter 25; or
  - 3. A registered nurse licensed under A.R.S. Title 32, Chapter 15.
- **E.** Before implementing this rule, an emergency medical services provider or an ambulance service shall notify the Department in writing of the intent to implement the rule.
- **F.** An emergency medical services provider or an ambulance service that implements this rule shall make available for Department review and inspection written records relating to the transport of an emergency medical patient under subsections (B), (C), and (D).

#### NOTICE OF EXEMPT RULEMAKING

#### TITLE 9. HEALTH SERVICES

# CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

#### **PREAMBLE**

1. Sections Affected Rulemaking Action

R9-25-801 Amend
Exhibit 1 Repeal
Exhibit 2 Repeal
Exhibit 3 Repeal
Exhibit 4 Repeal
R9-25-806 New Section

<u>2.</u> The specific authority for rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 36-136(F), 36B2202(A), 36-2205(C), and 36-2209(A)

Implementing statute: A.R.S. § 36-2205(A)

3. The effective date of the rule:

October 5, 2001

4. A list of all previous notices appearing in the Register addressing the exempt rule:

None

5. The name and address of agency personnel by whom persons may communicate regarding the rulemaking:

Name: Kathleen Phillips, Administrator

#### **Notices of Exempt Rulemaking**

Address: Department of Health Services, Office of Administrative Rules

1740 W. Adams, Suite 102

Phoenix, AZ 85007

Telephone: (602) 542-1264 Fax: (602) 364-1150

or

Name: Dr. Judi Crume, Bureau Chief

Address: Department of Health Services, Bureau of Emergency Medical Services

1651 E. Morten, Suite 120

Phoenix, AZ 85020

Telephone: (602) 861-0708 Fax: (60) 861-9812

### 6. An explanation of the rule, including the agency's reason for initiating the rule, including the statutory citation to the exemption from the regular rulemaking procedures:

R9-25-801 and Exhibits 1, 2, 3, and 4:

The rulemaking updates the section to make it consistent with Department rules governing vaccine-preventable diseases in 9 A.A.C. 25, Article 7 and with immunization recommendations issued by U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Immunization Program. The rulemaking repeals Exhibits 1, 2, 3, and 4 and cross references requirements regarding provision of information, written consent forms, and record keeping in 9 A.A.C. 25, Article 7.

#### R9-25-806

This rulemaking adds a new section that codifies the Department's current practices regarding the testing and evaluation of medical treatments, procedures, techniques, medications, and pieces of equipment that may be performed, administered, or used by an emergency medical technician. The testing is necessary to evaluate the safest and most current advances in medical technology and medications, thereby reducing the use of outdated or obsolete medical techniques and medications. The ultimate goal is to improve patient care. Based upon the results of the testing and evaluation, the Department can identify if changes are needed in rules authorized under A.R.S. § 36-2205.

The amendment of R9-25-801 and the addition of R9-25-806 were reviewed and accepted by representatives of the emergency medical services community and are recommended by the Medical Director of the Bureau of Emergency Medical Services.

A.R.S. § 36-2205(C) exempts this protocol from the provisions of A.R.S. Title 41, Chapter 6.

### 7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

#### 8. The summary of the economic, small business and consumer impact:

A.R.S. § 36-2205(C) provides exemption from the provisions of A.R.S. Title 41, Chapter 6.

### 9. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Not applicable

#### 10. A summary of the principal comments and the agency response to them:

Not applicable

### 11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

#### 12. Incorporation by reference and their location in the rules:

None

#### 13. Was this rule previously adopted as an emergency rule?

No

#### 14. The full text of the rule follows:

Section

#### TITLE 9. HEALTH SERVICES

# CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

#### ARTICLE 8. MEDICAL DIRECTION PROTOCOL FOR EMERGENCY MEDICAL TECHNICIANS

R9-25-801.	Protocol for Administration of Immunizations by Advanced Life Support Personnel a Vaccine, an Immuniz-
	ing Agent, or a Tuberculin Skin Test by an Intermediate Emergency Medical Technician or a Paramedic
Exhibit 1.	Immunization Screening Information-Immunization Program Repealed
Exhibit 2.	Immunization Brochures and Forms Repealed
Evhibit 2	Consent For Immunization Repealed

Exhibit 3. Consent For Immunization Repealed Vaccine Administration Repealed

R9-25-806. Testing of Medical Treatments, Procedures, Medications, and Techniques That May Be Administered or

Performed By an Emergency Medical Technician.

#### ARTICLE 8. MEDICAL DIRECTION PROTOCOL FOR EMERGENCY MEDICAL TECHNICIANS

### R9-25-801. Protocol for Administration of Immunizations by Advanced Life Support Personnel a Vaccine, an Immunizing Agent, or a Tuberculin Skin Test by an Intermediate Emergency Medical Technician or a Paramedic

A. Prior to administering any immunization, the advanced life support personnel shall:

- 1. Volunteer with or be employed by an agency who sponsors the immunization clinic;
- 2. Successfully complete an immunization administration training course that meets the standards established in rule;
- 3. Receive a letter of course completion, signed by the physician who approved the training curriculum, evidencing successful completion of immunization administration training that meets the standards established in rule;
- 4. Provide evidence of yearly continuing education in immunization administration, as established in rule.
- **B.** The administration of immunizations is not a prehospital emergency service activity. Therefore, the base hospital or administrative medical control authority shall not be responsible for and shall not provide medical direction or control to advanced life support personnel for the administration of immunizations unless it has a separate contract that meets the requirements of subsection (C) of this protocol.
- C. The agency which sponsors the immunization clinic and utilizes advanced life support personnel to administer immunizations shall execute a written contract with a physician licensed in Arizona and practicing medicine in general practice, pediatries, internal medicine, family practice, or emergency medicine. The contract shall authorize the physician to direct the immunization administration activities of the advanced life support personnel. The physician shall:
  - 1. Be accessible by phone, beeper, or in person at the times when immunizations are administered;
  - 2. Approve the training curriculum and either provide each student with a course completion letter or accept a course completion letter signed by another physician evidencing successful completion of immunization administration training.
- **D.** The advanced life support personnel shall:
  - 1. Only administer non-emergent, routine immunizations during a scheduled immunization clinic.
  - 2. Provide the "Immunization Screening Information" sheets, as shown in Exhibit 1, to each recipient who has legal capacity to consent. Provide the sheet to the parent or guardian of a recipient who does not have the legal capacity to consent.
  - 3. Provide each recipient, parent, or guardian with a copy of the "Important Information Statements" as shown in Exhibit 2 which describes the disease, who should receive the vaccine, the vaccine's side effects, and after care for all immunizations the recipient is to receive.
  - 4. Receive written consent for administration of each immunization, on the form shown in Exhibit 3. If the recipient of the immunization has legal capacity to consent, the recipient shall sign the form. If the recipient does not have the legal capacity to consent, the recipient's parent or legal guardian shall sign the form.
- **E.** The authorized immunizations shall include:
  - 1. Oral Polio (OP);
  - 2. Inactivated Polio (IPV);
  - 3. Diphtheria, Pertussis, Tetanus (DPT);
  - 4. Diphtheria, Tetanus (DT);
  - 5. Tetanus, diphtheria (Td);
  - 6. Haemophilus b Conjugate (Hib);

- 7. Hepatitis B (HBV);
- 8. Measles, Mumps, Rubella (MMR) or any combination of M, MR, or MMR;
- 9. Tuberculosis skin test (PPD).
- F. The immunizations shall be administered according to the dosage and vaccine administration procedure described in Exhibit 4 to this protocol.
- **G.** Record keeping shall be in accordance with A.A.C. R9-6-702(F) and R9-6-703 and statutes mandating immunizations record keeping.
- **A.** In this rule "immunization clinic" means an event organized for the purpose of administering a vaccine, an immunizing agent, or a tuberculin skin test.
- **B.** An intermediate emergency medical technician or a paramedic certified under 9 A.A.C. 25, Article 6 is authorized to administer:
  - 1. A vaccine or an immunizing agent recommended by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Immunization Program; or
  - 2. A tuberculin skin test.
- C. An intermediate emergency medical technician or a paramedic certified under 9 A.A.C. 25, Article 6 may administer a vaccine, an immunizing agent, or a tuberculin skin test:
  - 1. After complying with the requirements in R9-25-609;
  - 2. For an agency sponsoring an immunization clinic:
  - 3. During a scheduled immunization clinic; and
  - 4. Under the medical direction of a medical director under contract with the agency sponsoring the immunization clinic, as required in subsection (E).
- **D.** An intermediate emergency medical technician or a paramedic who administers a vaccine or immunizing agent authorized in subsection (B) shall:
  - 1. Provide immunization information and written immunization records consistent with and as required in R9-6-702;
  - 2. Receive signed, written consent consistent with and as required in R9-6-702; and
  - 3. Provide documentary proof of immunity consistent with and as required in R9-6-703.
- E. The agency sponsoring an immunization clinic shall have a written contract with a medical director who:
  - 1. Meets the requirements in R9-25-609 (1)(a), and
  - 2. <u>Is accessible by telephone, beeper, two-way radio, or in person at the time when the vaccine or immunizing agent is administered.</u>

#### Exhibit 1. Immunization Sercening Information - Immunization Program Repealed

		YES	NO	DON'T KNOW
1	Are you or the person being immunized sick with something more serious that a minor illness, such as a cold?			
2	Have you or the person being immunized ever had a reaction after an immunization that required a visit to the doctor or hospital?			
3	Are you or the person being immunized allergic to the antibiotics neomycin or strepto- mycin?			
4	Are you or the person being immunized allergic to eggs?			
5	Has the person to be vaccinated or anyone in the household had or have any of the following conditions?			
	• HIV-positive / AIDS			
	• Infections due to immunity problems			
	• Treatment for cancer			
	• Leukemia			
	• Is on a steroid/cortisone medication (prednisone)			
	Organ transplant			
6	Have you or the person being immunized received gamma globulin in the past three (3) months?			
7	Have you or the child to be immunized ever had a serious reaction to a product containing thimerosal (a mercurial antiseptic)?			
8	Is the girl/woman to be immunized pregnant or plans to become pregnant in the next three (3) months?			

#### Exhibit 2. Immunization Brochure and Forms Repealed

WHAT IS HAEMOPHILUS INFLUENZAE TYPE b DISEASE? Haemophilus influenzae type b (Haemophilus b) is a bacterium which can cause serious disease, especially in children under 5 years of age. This bacterium is not the cause of the "flu" (influenza). In the United States, Haemophilus b causes about 12,000 cases of meningitis (infection of the covering of the brain) each year, mostly in children under 5 years of age. About 1 child in every 20 with meningitis caused by Haemophilus b dies of it and about 1 out of 4 has permanent brain damage. Haemophilus b can also cause pneumonia and infections of other body systems such as blood, joints, bone, soft tissue under the skin, throat, and the covering of the heart. About 1 in every 200 children in the United States will have a moderate to severe disease caused by Haemophilus b before their fifth birthday. Serious Haemophilus b disease is most common in children between 6 months and 1 year of age. About half of all Haemophilus b disease in children happens during the first year of life. The disease still occurs with some frequency in older preschool children. Thirty percent of severe disease occurs in children 18 months of age or older.

HAEMOPHILUS b CONJUGATE VACCINE: There are at least three types of licensed Haemophilus b conjugate vaccines available for use. All of the vaccines contain the outer coating of the Haemophilus b bacterium which is the part that gives protection against the disease. All of the vaccines are approved for use in children 15 months of age and older. There are some differences among the vaccines. However, all of the vaccines are considered to be effective. Not all of the vaccines are approved for use in infants. The Haemophilus b conjugate vaccine is given by injection. More than 90% of infants respond to 3 doses of the vaccine approved for infants by making substances in their blood (antibodies) that provide long-term protection against the severe diseases caused by Haemophilus b bacteria. However, several days are required for any protection to be obtained after immunization. Whether the vaccine provides protection against ear infections caused by Haemophilus b bacteria is not known. It does not protect against disease caused by other types of Haemophilus. The vaccine does not protect against meningitis caused by other bacteria. The vaccine is not known to cause Haemophilus disease. The Haemophilus b conjugate vaccine first became available in 1988 and its use for infants first became recommended in 1990.

WHO SHOULD RECEIVE THE HAEMOPHILUS b CONJUGATE VACCINE?

- 4. All children should receive the vaccine for infants at 2, 4, and 6 months of age. Also, a dose of any of the approved Haemophilus b conjugate vaccines should be given at 15 months of age, or as soon as possible thereafter.
- 2. Unvaccinated children 15-60 months of age should receive a single dose of conjugate vaccine.
- 3. Children 60 months of age and older and adults normally do not need to be immunized.

#### ARIZONA DEPARTMENT OF HEALTH SERVICES

### IMPORTANT INFORMATION ABOUT HAEMOPHILUS INFLUENZAE TYPE b DISEASE AND HAEMOPHILUS b CONJUGATE VACCINE Please read this carefully

I have read or have had explained to me the information on this form about Haemophilus b conjugate vaccine. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks of the Haemophilus b conjugate vaccine and request that it be given to me or to the person named below for whom I am authorized to make this request.

#### **INFORMATION ABOUT PERSON TO RECEIVE VACCINE (Please print)**

NAME: Last, Firs	st, MI	BIRTHDATE:	AGE:				
ADDRESS:	STREET	COUNTY:					
CITY: STATE: Z							
SIGNATURE OF	PERSON TO REC	ZETVE VACCINE OR PE	ERSON DATE				
<b>AUTHORIZED</b> 7	TO MAKE THE RE	EQUEST:	:				

#### **FOR CLINIC USE**

CLINIC IDENTIFICATION:		DATE VACCINATED:
MANUFACTURER AND	LOT	SITE OF INJECTION:
NO:		

#### **POSSIBLE SIDE EFFECTS FROM THE VACCINE:**

The Haemophilus b conjugate vaccine has few side effects. Information about the vaccine now available in the United States indicates that about 2 out of every 100 infants who receive the vaccine may have a fever higher than 101° F, 2 out of every 100 may have redness in the area where the vaccine was given; and 1 out of every 100 may have swelling or warmth in the area where the vaccine was given. These reactions begin within 24 hours after the shot is given, but generally go away by 48 hours after immunization. As with any vaccine or drug, there is a rare possibility that other serious problems or even death could occur after receiving the Haemophilus b conjugate vaccine.

# WARNING-SOME PERSONS SHOULD NOT TAKE THIS VACCINE WITHOUT CHECKING WITH A DOCTOR:

- · Anyone who is sick right now with something more serious than a minor illness such as a common cold.
- Anyone who has had a serious reaction to a product containing thimerosal, a mercurial antiseptic included in one of the vaccines that is in use.
- Anyone who has had an allergic reaction to a vaccine containing diphtheria toxoid so serious that it required medical treatment.

QUESTIONS If you have any questions about Haemophilus b disease or Haemophilus b conjugate vaccine, please ask now or call your doctor or health department before you sign this form.

#### WHAT TO LOOK FOR AND DO AFTER THE VACCINATION:

As with any serious medical problem, if the person has a serious or unusual problem after getting the vaccine, call a doctor or get the person to a doctor promptly.

If the person who received the conjugate vaccine gets sick and visits a doctor, hospital, or clinic during the 4 weeks after immunization, please report it to:

#### Please read this pamphlet before you or your child gets a vaccine!

Before vaccines were available, most children caught pertussis. Also, hundreds of people became ill with tetanus each year and thousands became ill with diphtheria.

The benefits of the vaccines to prevent these three diseases are greater than the possible risks for almost all people. A person who receives vaccines benefits from the protection they provide. When many people are vaccinated, everyone benefits because the chance for spread of disease is reduced.

These diseases may cause serious health problems. Therefore, it is important to be protected by vaccine shots. Usually, the vaccines for all three diseases are combined and are given together as one shot. This is called the DTP vaccine. DTP vaccine is usually given 5 times before a child reaches age 7 years.

Every vaccine has risks as well as benefits. Most problems that happen after receiving vaccines are mild, but a few people will have a serious problem. While most infants and children under 7 years of age should get the DTP, a few should delay getting this vaccine and a few others should get the DT vaccine (diphtheria and tetanus vaccine) instead. Another tetanus and diphtheria vaccine (Td) is used to protect older children and adults. Tetanus vaccine (T) is still used by some doctors, but the combined Td vaccine is recommended by most experts.

This pamphlet tells you more about:

The diseases diphtheria, tetanus, and pertussis page 1
The benefits of the vaccines page 2

The risks of the vaccines page 3

When your child should routinely get vaccines page 4

When your child should delay getting or not

get the DTP vaccine pages 5 & 6

What to look for and to do after the shot pages 7 & 8

#### WHAT ARE THESE DISEASES?

PERTUSSIS, sometimes called whooping cough, may be a mild or serious disease. It is very easily passed from one person to another. Pertussis can cause spells of coughing and choking that make it hard to eat, drink, or breathe. The coughing can last for several weeks.

The information on pertussis that follows is based on cases that were reported from doctors and health-care providers. In recent years, as many as 4,200 cases of pertussis have been reported yearly in the United States and outbreaks still occur. Many cases, including those with less serious illness, do not get reported.

Pertussis is most dangerous to babies (children less than 1 year old). Even with modern medical care, complications occur. About half of the babies reported to have pertussis are so sick that they must go into the hospital. As many as 16 out of 100 babies with pertussis get pneumonia, and as many as 2 out of 100 may have convulsions (seizures, fits, spasms, twitching, jerking, or staring spells). About 1 baby out of 200 has brain problems that may last all his or her life. About 1 out of every 200 babies with pertussis dies of it. Serious illness is less likely in older children and adults.

DIPHTHERIA is a very serious disease. It can make a person unable to breathe, cause paralysis, or heart failure. About 1 out of every 10 people who get diphtheria dies of it.

Only a few cases of diphtheria were reported in the United States during the past few years. This is mostly because people have had shots to protect them.

TETANUS, sometimes called lockjaw, is a very serious disease that can occur after a cut or wound lets the germ into the body. Tetanus makes a person unable to open his or her mouth or swallow, and causes serious muscle spasms. People with tetanus usually have to stay in the hospital for a long time. In the United States, tetanus kills 3 out of every 10 people who get the disease. Since 1975, only 50 to 90 cases of tetanus have been reported each year.

Almost no cases occur in children or young adults because children and young adults have taken the shots and are usually protected.

#### WHAT ABOUT THE VACCINES AND THEIR BENEFITS?

The vaccines to protect children younger than 7 years old against all 3 diseases are usually given together as one shot. This is called the DTP vaccine (Diphtheria, Tetanus, and Pertussis). Most children should get 5 DTP shots before they go to school. Most babies should get 3 DTP shots by 6 months of age.

#### Three or more DTP shots keep:

- 70 to 90 children out of 100 from getting pertussis if exposed to it, and usually protect the child through the elementary school years. The others who have had the DTP vaccine but get pertussis usually have a milder illness than if they had not had the vaccine.
- At least 85 children out of 100 from getting diphtheria for at least 10 years.
- At least 95 children out of 100 from getting tetanus for at least 10 years.

Pertussis vaccine should not be given to a few children. Other vaccines are available for these children and for adults:

- DT vaccine (Diphtheria and Tetanus) is given to children under age 7 years who should not receive pertussis vaccine.
- Td vaccine (Tetanus and diphtheria) is specially made for children age 7 years and older and for adults.

#### WHAT ARE THE RISKS OF THESE VACCINES?

**DTP** 

Most children have little or no problem from the DTP shot. Many children will have fever or soreness, swelling, and redness where the shot was given. Usually these problems are mild and last 1 to 2 days. Some children will be eranky, drowsy, or not want to eat during this time.

Less often -- that is, following 1 DTP shot in 100 to 1 shot in 1,000 -- a more serious problem can happen:

- Crying without stopping for 3 hours or longer
- A temperature of 105° F or higher
- · An unusual, high-pitched cry

Even less often -- following 1 DTP shot in 1,750 -- a child may have:

- A convulsion (seizures, fits, spasms, twitching, jerking, or staring spells), usually from high fever that may happen after the shot
- Shock-collapse (become blue or pale, limp, and not responsive)

Rarely, brain damage that lasts for the child's life has been reported after getting DTP. However, most experts now agree that DTP has not been shown to be a cause of brain damage. If DTP ever causes brain damage, then such an event would be very rare. There is no test that can tell in advance if your child will have any of these problems following DTP vaccination.

#### DT, Td, and T

DT, Td, and T vaccines cause few problems. They may cause mild fever or soreness, swelling, and redness where the shot was given. These problems usually last for 1 to 2 days, but this does not happen nearly as often as with DTP vaccine. Sometimes, adults who get these vaccines too often can have a lot of soreness and swelling where the shot was given.

There is a rare chance that other serious problems or even death could occur after getting DTP, Pertussis, DT, T, or Td. Such problems could happen after taking any medicine or after receiving any vaccine.

#### WHEN SHOULD YOUR CHILD GET THE DTP VACCINES AND OTHER VACCINES?

Below are all of the vaccines that most infants and children should get and the age when most experts suggest they should get each dose of vaccine.

#### RECOMMENDED SCHEDULE OF VACCINATIONS FOR ALL CHILDREN Vaccine 2 Months 12 15 4-6 Years Months Months Months Months (Before School Entry) DTP DTP DTP DTP DTP\* DTP **POLIO POLIO** POLIO POLIO\* **POLIO MMR** MMR¶ MMR HIB Option 1§ HIB HIB HIB HIB Option 2§ HIB HIB HIB

Vaccine	Birth	1-2	4	6-18 Months	
		Months	Months		
НВ					
Option 1	ΉB	HB?		HB?	
Option 2		HB?	HB?	HB?	

DTP: Diphtheria, Tetanus, and Pertussis Vaccine

Polio: Live Oral Polio Vaccine drops (OPV) or Killed (Inactivated) Polio Vaccine shots (IPV)

MMR: Measles, Mumps, and Rubella Vaccine

#### **Notices of Exempt Rulemaking**

HIB: Haemophilus b Conjugate Vaccine

HB: Hepatitis B Vaccine

\* Many experts recommend these vaccines at 18 months

In some areas this dose of MMR vaccine may be given at 12 months.

Many experts recommend this dose of MMR vaccine be given at entry to middle school or junior high school.

HIB vaccine is given in either a 4-dose schedule (1) or a 3-dose schedule (2), depending on the type of vaccine used.

Hepatitis B vaccine can be given simultaneously with DTP, Polio, MMR, and Haemophilus b Conjugate Vaccine at the same visit.

#### ARE THE BENEFITS OF THE VACCINES GREATER THAN THE RISKS?

Yes, for almost all people.

Children, especially infants, who catch pertussis are often seriously ill. People with diphtheria or tetanus usually are seriously ill. Most people who have had 3 or more shots of DTP are protected from these diseases for many years. If children have the DTP shots but get pertussis, the illness is usually milder than if they had not had the shots. The number of children who have had a serious problem after receiving DTP is unknown, but is probably very small.

Experts believe that most children should receive DTP shots. If a child should not receive DTP, the child should usually receive DT. After reading this pamphlet and talking with your doctor or nurse, you can decide together what is best for your child.

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#### WHEN SHOULD A SHOT BE DELAYED?

There are several reasons for a child to delay getting the DTP shot. If the child:

- Is sick with something more serious than a minor illness such as a common cold, delay the vaccination until your child is better.
- Has ever had a convulsion or other brain problem or seems not to be developing normally (until it is clear that your child is not getting worse or having more convulsions).

Such children should be carefully examined by a doctor before a decision is made.

If your child is sick or if you are not sure if a shot should be delayed, talk to your doctor or nurse. Then you can decide together what is best for your child.

#### WHEN SHOULD THE DTP VACCINE NOT BE GIVEN?

Your child should not get another DTP shot if any of the problems listed below happened after an earlier DTP and had no other obvious cause. Talk with your doctor or nurse about any of these problems.

- Serious problems of the brain within 7 days after getting DTP.
- Serious allergic problem (swelling in the mouth, throat, or face, or difficulty breathing) within a few hours after getting DTP.
- The presence of a brain problem that is getting worse, such as uncontrolled convulsions.

Many experts believe that a child should not get another DTP shot if any of the problems listed below happened after an earlier DTP shot and had no other obvious cause. However, for some children, the benefits outweigh the risks. Talk with your doctor or nurse about any of these problems.

- Temperature of 105° F or higher within 2 days after getting DTP.
- Shock-collapse (becoming blue or pale, limp and not responsive) within 2 days after getting DTP.
- Convulsion within 3 days after getting DTP.
- Crying that cannot be stopped and which lasts for more than 3 hours at a time within the 2 days after getting DTP.

If you know or think that any of these problems happened after getting DTP, tell a doctor or nurse before that child receives another DTP or any other vaccine. If a child should not be given DTP, usually the child should get DT vac-

# Arizona Administrative Register Notices of Exempt Rulemaking

eine instead.
SHOULD PREGNANT WOMEN RECEIVE Td?  Babies born under unclean conditions to women who have no protection against tetanus have an increased risk of getting tetanus as newborns. This can be prevented by giving Td vaccine to women. Women who have not received Td or T earlier should be given the vaccine when they are pregnant.
Td and T vaccines are not known to cause special problems for pregnant women or their unborn babies. While doctors usually do not recommend giving any drugs or vaccines to pregnant women, a pregnant woman who needs Td vaccine should get it.
WHICH CHILDREN MAY BE MORE LIKELY TO HAVE A CONVULSION AFTER RECEIVING DTP? The chance of a child having a convulsion with fever after receiving DTP vaccine is up to 9 times greater if the child has had a convulsion before. It is about 3 times greater if the child's brother, sister, or parent has ever had a convulsion.
Most experts agree that unless the convulsion occurred within 3 days after getting DTP vaccine, children who have had a convulsion should still get the DTP vaccine. Also children who have a family member who has had a convulsion should get the DTP vaccine.
It is usually the fever that causes the convulsion. Most experts believe that convulsions with fever do not cause any permanent damage to the child.
Be sure to tell the doctor or nurse who is giving the shot about any history of convulsions. Talk with them about the medicines or other measures to reduce fever and soreness from the vaccines.
WHAT TO LOOK FOR AND TO DO AFTER THE SHOT  Talk with the doctor or nurse who gives the shot about taking medicines or other measures to reduce fever and soreness from the vaccine.
This pamphlet lists the problems (on pages 3, 6, and 7) that may occur after receiving DTP or other shots for diphtheria, tetanus, or pertussis.
As with any serious medical problem, if the person has a serious or unusual problem after getting the vaccine, CALL A DOCTOR OR GET THE PERSON TO A DOCTOR PROMPTLY.
If you or your child does have a reaction to the vaccine, you can help your doctor by writing down exactly what happened.
Use this form or write on a piece of paper exactly what happened, what day it happened, and the time it happened.
Type of Vaccine and Date Received:
Problems Day and Time Problem Started

#### **Notices of Exempt Rulemaking**

#### HAVE THE PROBLEM REPORTED:

The Public Health Service is interested in finding out if any serious problems may be related to DTP, Pertussis, DT, T, or Td vaccines, especially those that occur within 4 weeks after the shot.

If you believe that the person receiving the vaccine had a serious problem or died because of the shot:

#### Call this number:

And ask the doctor or health department to report the problem on a Vaccine Adverse Event Report form. If you think the problem was not reported, you should report the problem yourself. You can get the form by calling this toll-free number: 1-800-822-7967.

#### **GET INFORMATION ABOUT POSSIBLE HELP:**

A U.S. government program provides compensation for some persons injured by vaccines. For more information, call this toll-free number:

1-800-338-2382

OR contact:

The U.S. Claims Court, 717 Madison Place, NW, Washington, DC 20005, (202) 633-7257

Please read this pamphlet before you or your child gets a dose of vaccine!

As recently as the 1950s, polio was a common disease in the United States. Parents feared this disease for good reasons. In 1952, more than 20,000 people were paralyzed by polio. Because children and adults now receive vaccines, there are only a few cases of polio each year in the United States.

The benefits of polio vaccine are greater than any possible risks for almost all people. A person who receives vaccines benefits from the protection they provide. When many people are vaccinated everyone benefits because the chance of spreading the disease is reduced.

Every vaccine and medicine has risks as well as benefits. Most vaccine reactions are mild. But a few people may get very sick after getting vaccines. Some should not get the polio vaccine or should delay getting it.

There are 2 kinds of vaccines that can protect you or your child against polio. Read this pamphlet before you or your child gets the vaccine. Talk it over with your doctor or nurse. Then, together, you can decide what is best for you or your child.

This pamphlet tells you more about:

The disease polio page 1

The benefits of the vaccines page 2

The risks of the vaccines page 3

When your child should routinely get vaccines page 4

When the vaccines should be delayed or not be given page 6

What to look for and to do after getting the polio vaccine pages 7 & 8

WHAT IS POLIO?

Polio is a very dangerous disease caused by a virus. Some children and adults who get a serious case of polio become paralyzed. This means that they are unable to move parts of their bodies. They may even die from the disease.

The serious cases of polio cause severe muscle pain and sometimes make the person unable to move one or both legs or arms and may make it difficult to breathe without the help of a machine, Mild cases of polio may last only a few days and may cause the person to have fever, sore throat, stomachache, and headache.

There are no drugs or other special treatments that will cure people who get polio. How sick people get with the disease and how much they recover are different for each person. Most people who are paralyzed by polio will have some weakness in an arm or leg for the rest of their lives. Many of these people will be seriously disabled.

Although there are few cases of polio in the United States now, there are still many thousands of cases of polio each year in other countries. Therefore, it is important to protect our children with vaccines so that they cannot get the disease when someone brings the virus into the United States from another country.

#### WHAT ABOUT THE VACCINES AND THEIR BENEFITS?

There are 2 types of polio vaccines. Most experts recommend the live oral polio vaccine, which is called OPV. "Live" means that the polio virus used in the vaccine is still alive but has been made very weak. This type of vaccine is given as drops in the mouth. The other vaccine is called IPV (inactivated polio vaccine). "Inactivated" means that the polio virus used in the vaccine has been killed. This type of vaccine is given as a shot.

At least 90 out of every 100 people who get 3 or more doses of either OPV or IPV will be protected against polio. For healthy children and teenagers up to their 18th birthday, most experts recommend OPV drops rather than IPV shots. This is because OPV is easier to take and is more effective in preventing the spread of polio.

The best way to be protected against polio is to get 4 doses of polio vaccine. Most babies should get 2 doses by 4 months of age and a third dose at 15 to 18 months of age. The fourth dose is given at 4 to 6 years of age.

These doses may be the drops given in the mouth (OPV) or the shots (IPV).

If there is a case of polio in your neighborhood or where your child goes to school or child-care, your child may need another dose of vaccine. Your doctor may also suggest that your child get another dose before taking a trip to any country where polio is common.

Adults who are doing to countries where polio is common should also get at least one dose of either OPV (it they have had this type of vaccine before) or IPV. If an adult has never had OPV, he or she should get IPV. It would be best to get 3 doses before going. If there is only enough time to get one dose, either OPV or IPV should be given before leaving the country.

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#### WHAT ARE THE RISKS OF THESE VACCINES?

Both OPV and IPV vaccines cause problems in very few people.

#### OPV drops:

- Very rarely, OPV causes polio in the person who gets the drops.
- For the person who gets the vaccine, the chance of becoming paralyzed is higher after getting the first dose of vaccine than after the second, third, or fourth doses. Paralysis after the first dose happens about once for every 1 million doses of drops given. But paralysis after later doses happens only about once for every 40 million doses given.
- OPV drops very rarely can cause polio in people who are in close contact with the person who gets the vaccine. This happens only to people not already protected by polio vaccine.
- The chance of a person in close contact with the one who gets the vaccine becoming paralyzed is higher after the first dose of vaccine than after the second, third, or fourth doses. Paralysis after the first dose happens about once for every 2 million doses of drops given. But paralysis after later doses happens only about once for every 14 million doses given. If the parent or other adult household contact of a child receiving OPV has never received polio vaccine, this person should consider, if possible, being vaccinated with IPV before or at the same time as the child. Vaccination of the child should not be delayed. Talk with your doctor or nurse if you have any questions.

#### IPV shots:

• IPV can cause a little soreness and redness where the shot was given.

There is a very rare chance that other serious problems or even death could occur after getting either vaccine. Such problems could happen after taking any medicine or after receiving any vaccine.

#### WHEN SHOULD YOUR CHILD GET THE POLIO VACCINE AND OTHER VACCINES?

Below are all of the vaccines that most infants and children should get and the age when most experts suggest they should get each dose of vaccine.

DECOM	(EMD)	ED CCHEDI	HEOEVA	CCINATI	ONG FOD	ALL CHILD	DEN	
RECOMIN	IENDI	ED SCHEDU	JLE OF VA	CCINAII	ONS FOR	ALL CHILD	KEN	_/_
			T		_	1		
Vaccine		2 Months	4	6	12	15	4-6 Years	
			Months	Months	Months	Months		
							(Before	School
							Entry)	
DTP		DTP	DTP	DTP		DTP*	DTP	
POLIO		POLIO	POLIO			POLIO*	POLIO	
MMR						MMR	MMR¶	
HIB								
Option		HIB	HIB	JHIB		HIB		
1§		HIB	HIB /		HIB			
Option								
2§		_						
Vaccine	Birt	1-2	4	6-18 Moi	nths			
	h/	Months	Months					
HB /								
Option 1	HB	HB?		HB?				
Option 2		HB?	HB?	HB?				

DTP: Diphtheria, Tetanus, and Pertussis Vaccine

Polio: Live Oral Polio Vaccine drops (OPV) or Killed (Inactivated) Polio Vaccine shots (IPV)

MMR: Measles, Mumps, and Rubella Vaccine

HIB: Haemophilus b Conjugate Vaccine

HB: Hepatitis B Vaccine

\* Many experts recommend these vaccines at 18 months.

In some areas this dose of MMR vaccine may be given at 12 months.

- \*Many experts recommend this dose of MMR vaccine be given at entry to middle school or junior high school.
- § HIB vaccine is given in either a 4-dose schedule (1) or a 3-dose schedule (2), depending on the type of vaccine used.
- ? Hepatitis B vaccine can be given simultaneously with DTP, Polio, MMR, and Haemophilus b Conjugate Vaccine at the same visit.

#### ARE THE BENEFITS OF THE VACCINES GREATER THAN THE RISKS?

Yes, for almost all people.

Polio can be a very serious disease. Almost all people who get the vaccines are protected from this disease. Only a small number of people have problems after getting the vaccines. The problems that may happen after receiving vaccine occur much less often than when the person has the disease.

Experts believe that most people should receive polio vaccine. After reading this pamphlet and talking with your doctor or nurse, you can decide whether there is any reason for you or your child to delay or not get the polio vaccine.

There are several reasons why some people may need to delay getting polio vaccine or should not get it at all.

WHEN SHOULD THE VACCINES BE DELAYED?

Polio drops (OPV) or shots (IPV) should be delayed for any person who:

• Is sick with something more serious than a minor illness such as a common cold. Delay the vaccination until the person is better.

#### WHEN SHOULD THE VACCINES NOT BE GIVEN?

IPV should be given instead of OPV to a person who:

- Is born with or develops any disease that makes it hard for the body to fight infection, such as cancer, leukemia, or lymphoma (cancer of the lymph glands),
- Has AIDS or infection with the virus that causes AIDS.
- Is taking special cancer treatments such as x-rays or drugs or is taking other drugs, such as prednisone or steroids, that make it hard for the body to fight infection.

The close contact that occurs in the home makes it possible for the virus that is present in OPV drops to be passed on to another member of the household. Doctors usually advise that if any person in the home has any of the medical conditions listed above, IPV should be used instead of DPV.

IPV should not be given to a person who:

• Has had an allergy problem with the antibiotics neomycin or streptomycin so serious that it required treatment by a doctor-

Be sure to talk to the doctor or nurse about which polio vaccine you or your child should get.

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#### SHOULD PREGNANT WOMEN RECEIVE THE VACCINES?

The polio vaccines are not known to cause any problems to the unborn babies of pregnant women. Doctors usually do not recommend giving any drugs or vaccines to pregnant women unless there is a special need. However, if a pregnant woman needs immediate protection, OPV is recommended.

#### WHAT TO LOOK FOR AND TO DO AFTER GETTING THE POLIO VACCINE:

This pamphlet lists the problems (on pages 3, 6 and 7) that may occur after receiving either OPV or IPV.

As with any other serious medical problem, if the person has a serious or unusual problem after getting the vaccine, CALL A DOCTOR OR GET THE PERSON TO A DOCTOR PROMPTLY.

Please read this pamphlet before you or your child gets a vaccine!

Before vaccines were available to protect against measles, mumps, and rubella, nearly everyone caught these diseases while growing up. The use of vaccines against these diseases has greatly reduced the number of people getting these illnesses.

The benefits of the vaccines to prevent these three diseases are greater than the possible risks for almost all people. A person who receives vaccines benefits from the protection they provide. When many people are vaccinated, everyone benefits because the chance for spread of disease is reduced.

Serious health problems are caused by these diseases. Therefore, it is important to be protected by the vaccines. Usually, vaccines for all 3 diseases are combined and are given together as 1 shot, called the MMR vaccine. Usually it is given 2 times, first at 15 months of age and again before school entry (4 to 6 years of age), or before entering middle school or junior high school.

Every vaccine and medicine has both benefits and risks. Most problems that occur after vaccines are mild, but a few people may have a serious problem. While most people should get MMR, a few people should not, and a few others should delay getting the vaccine.

This pamphlet tells you more about:

The diseases measles, mumps, and rubella pages 1 & 2

The benefits of the vaccines page 2

The risks of the vaccines pages 3 & 4

When your child should routinely get vaccines page 5

When the vaccines should be delayed or not be given page 6

What to look for and to do after the shot pages 7 & 8

#### WHAT ARE THESE DISEASES?

MEASLES is a serious disease. It is very easily passed from one person to another. It causes a high fever, cough,

and a rash and lasts for 1 to 2 weeks. In recent years, 3,000 to 28,000 cases of measles have been reported yearly in the United States and outbreaks still occur. One out of every 10 children who catch measles will also have an ear infection or pneumonia.

Measles can also cause an infection of the brain that could lead to convulsions (seizures, fits, spasms, twitching, jerking, or staring spells), hearing loss, and mental retardation. This happens to about 1 out of every 1,000 children reported to have the disease. In the United States, 1 child out of every 500 to 10,000 who gets measles dies from it.

Babies and adults who eatch measles are often much sieker and are more likely to suffer longer or die than elementary school children and teenagers with measles.

MUMPS causes fever, headache, and swollen, painful glands under the jaw. Mumps sometimes can be a very serious disease. It lasts for several days and it is easily passed from person to person. In recent years, 4,500 to 13,000 eases of mumps have been reported each year in the United States and outbreaks still occur.

Mumps can cause a mild inflammation of the coverings of the brain and spinal cord (meningitis) in about 1 person in every 10 who get it. Swelling or inflammation of the brain is reported in about 1 case out of every 200. Before there was a mumps vaccine, many children had hearing loss caused by mumps. About 1 out of every 4 teenage or adult males with mumps will have a painful swelling of the testicles for several days. This usually does not make the person unable to father children.

Teenagers and adults, especially males, who eatch mumps are often much sicker and more likely to suffer longer than children do.

RUBELLA is also called German measles. In recent years, only a few hundred cases of rubella were reported each year. It is usually a mild disease that lasts for a short time. BUT if a pregnant woman catches the disease, rubella is very dangerous to her unborn baby. Up to half of the women who catch rubella when they are pregnant will lose their babies or have babies born with heart disease, or babies who will be blind or deaf, or who have problems with learning. In the United States, before there was a rubella vaccine, many thousands of babies with these serious health problems were born to mothers who caught rubella while they were pregnant.

People who catch rubella usually have mild fever, swollen glands in the neck, and a rash that lasts up to 3 days. Rubella may cause soreness in the joints and swelling of the joints (arthritis). This may happen in up to 70 out of every 100 women. Usually this lasts only for a week or two but in rare cases it may last for months or years, or may come and go.

People who do not get the rubella vaccine are in danger of catching rubella and passing it on to a pregnant woman. About 1 out of every 10 women in the United States is not protected against rubella.

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#### WHAT ABOUT THE VACCINES AND THEIR BENEFITS?

The vaccines to protect against all 3 diseases are usually given together in 1 shot, called the MMR vaccine. One MMR shot protects 90 to 98 people out of every 100 against measles, mumps, and rubella if they get the vaccine at the right age. Usually a child gets the first MMR at 15 months of age, but sometimes it should be given at 12 months of age, or even earlier during an outbreak. To protect the few children not protected by the first MMR, a second MMR is recommended when a child enters school for the first time or when a child enters middle school or junior high school.

These vaccines protect nearly all people for a very long time, probably for life. However, if an outbreak of measles occurs, doctors may recommend a second MMR shot. Teenagers and adults who do not know if they are protected against these diseases should ask their doctor or clinic about getting the MMR.

#### WHAT ARE THE RISKS OF THESE VACCINES?

Most people who get the MMR vaccine will not have a problem. Others will have minor problems such as a sore or red arm that lasts for 1 to 2 days. Rarely a person may have a serious problem.

If you or your child receives the MMR, there is a chance that any of the problems listed below could happen. If problems occur, they almost always happen after the first shot. If you or your child receives only the measles vaccine, or the mumps vaccine, or the rubella vaccine, you should only look for the problems listed for the vaccine received

Mild or Moderate Problems From the Vaccines

**MEASLES VACCINE:** 

#### **Notices of Exempt Rulemaking**

- A rash may occur from 1 to 2 weeks after receiving the measles vaccine About 5 children out of every 100 will get a rash.
- A fever of 103° F or higher after receiving the first shot of measles vaccine, even though the child may not act sick. About 5 to 15 young children out of every 100 who receive the vaccine get such a fever. This could happen from 1 to 2 weeks after receiving the vaccine and usually lasts 1 or 2 days. The fever occurs less often after a second shot.

#### **MUMPS VACCINE:**

• A little swelling of the glands in the cheeks and under the jaw that lasts for a few days. This could happen from 1 to 2 weeks after getting the mumps vaccine. This happens rarely.

#### RUBELLA VACCINE:

- Swelling of the lymph stands in the neek or a rash that lasts 1 or 2 days. This could happen 1 to 2 weeks after getting the rubella vaccine in about 1 child out of every 7 who get the vaccine.
- Mild pain or stiffness in the joints that may last up to 3 days. This could happen from 1 to 3 weeks after getting the shot. This problem happens to about 1 child out of every 100 who get the shot and to about 25 adults out of every 100. Women have this problem more than men and it may happen in up to 40 women out of every 100. Rarely, pain or stiffness can last for months or longer and can come and go.
- Painful swelling of the joints (arthritis) happens to fewer than 1 child out of every 100 who get the rubella vaccine. About 10 adults out of every 100 can also have this problem, which usually lasts a few days to a week. Rarely, this swelling has been reported to last longer, or to come and go. Damage to the joints is very rare.
- Pain or numbness, or "pins and needles" feeling in the hands and feet that lasts for a short time. This happens rarely.

#### More Serious Problems From These Vaccines

- Children 6 months through 6 years of age who get the vaccines can, in rare cases, have a brief convulsion (fits, seizures, spasms, twitching, jerking, or staring spells). This usually occurs 1 to 2 weeks later and usually comes from the fever caused by the measles vaccine. Very rarely, hearing loss has been reported, but it is not known whether hearing loss is ever caused by these vaccines. Very rarely, a person can have inflammation of the brain after receiving the vaccine. This usually clears up completely. These brain problems have been reported to happen about 1 time for every million MMR shots given.
- There is a rare chance that other serious problems and even death could occur after getting the vaccines. Such problems could happen after taking any medicine or after receiving any vaccine.

### ARE THE BENEFITS OF THE VACCINES GREATER THAN THE RISKS?

Yes, for almost all people.

These diseases make some people very ill. Almost all people who get the vaccines are protected from these diseases. A small number of people have problems after getting the vaccines. The problems that may happen after receiving the vaccine occur much less often than when a person has the disease.

Experts believe that most people should receive these vaccines. After reading this pamphlet and talking with your doctor or nurse, you can decide whether there is any reason for you or your child to delay getting or not get the vaccine.

#### WHEN SHOULD YOUR CHILD GET THE MMR VACCINES AND OTHER VACCINES?

Below are all of the vaccines that most infants and children should get and the age when most experts suggest they should get each dose of vaccine.

#### RECOMMENDED SCHEDULE OF VACCINATIONS FOR ALL CHILDREN

Vaccine	2 Months	4 Months	6 Months	12 Months	15 Months	4-6 Years
						(Before School Entry)
DTP	DTP	DTP	DTP		DTP*	DTP
POLIO	POLIO	POLIO	POLIO		POLIO*	POLIO
MMR					MMR	MMR¶
HIB Option 1§ Option 2§	HIB HIB	HIB HIB	НІВ	НІВ	НІВ	

Vaccine	Birth	1-2	4	6-18 Months	
		Months	Months		
НВ					
Option 1	HB	HB?		HB?	
Option 2		HB?	HB?	HB?	

DTP: Diphtheria, Tetanus, and Pertussis Vaccine

Polio: Live Oral Polio Vaccine drops (OPV) or Killed (Inactivated) Polio Vaccine shots (IPV)

MMR: Measles, Mumps, and Rubella Vaccine

HIB: Haemophilus b Conjugate Vaccine

HB: Hepatitis B Vaccine

\* Many experts recommend these vaccines at 18 months.

In some areas this dose of MMR vaccine may be given at 12 months.

Many experts recommend this dose of MMR vaccine be given at entry to middle school or junior high school.

§ HIB vaccine is given in either a 4-dose schedule (1) or a 3-dose schedule (2), depending on the type of vaccine used.

? Hepatitis B vaccine can be given simultaneously with DTP, Polio, MMR, and Haemophilus b Conjugate Vaccine at the same visit.

#### WHEN SHOULD THE VACCINES BE DELAYED OR NOT BE GIVEN?

There are several reasons some people may need to delay getting the MMR vaccine or not get the shot at all. These reasons also apply to measles vaccine, mumps vaccine, and rubella vaccine.

Tell the doctor or nurse if the person who is going to get the vaccine:

- Is siek with something more serious than a minor illness such as a common cold. Delay the vaccination until the person is better.
- Has ever had an allergy problem after eating eggs that was serious enough to require the attention of a doctor. This does not matter if the person is only receiving the rubella vaccine.
- Has had an allergy problem to an antibiotic called neomycin so serious that it required treatment by a doctor.
- Is born with or develops any disease that makes it hard for the body to fight infection such as cancer, leukemia, lymphoma (cancer of the lymph glands).
- Is taking special cancer treatments such as x-rays or drugs, or is taking other drugs such as prednisone or steroids that make it hard for the body to fight infection.
- Has received gamma globulin during the past 3 months.
- Is pregnant or thinks she is pregnant.

All people who do not get the vaccine because of one of the reasons listed above should check again with the doctor or nurse about getting the vaccines at a later time.

#### **Notices of Exempt Rulemaking**

#### SHOULD PREGNANT WOMEN RECEIVE THE VACCINES?

Women who are pregnant, who think they are pregnant, or who might get pregnant in the next 3 months, should not get MMR or other vaccines for measles, mumps, or rubella. This is recommended even though these vaccines are not known to cause problems for pregnant women or their unborn babies. It is safe, however, to give a shot to a ehild whose mother is pregnant.

If a woman is pregnant and does not know if she is protected against rubella, she should tell her doctor. A woman who receives any of these vaccines should not get pregnant for the next 3 months. A woman who needs protection against any of these diseases should be given the vaccines right after her baby is born.

WHICH PEOPLE MAY BE MORE LIKELY TO HAVE A CONVULSION AFTER RECEIVING MMR? The chance of a child having a convulsion with fever after receiving measles vaccine is small. However, the risk is up to 5 times greater if the child has ever had a convulsion before. It is also greater if the child's brother, sister, or parent has ever had a convulsion. Most experts agree that people who have had a convulsion should still get the MMR vaccine. Also, people who have a family member who has had a convulsion should get the MMR vaccine. The overall chance of convulsion after getting the vaccine is still rare. It is usually the fever that causes the convulsion. Most experts believe that convulsions with fever do not cause any permanent damage to the child. Be sure to tell the doctor or nurse who is giving the shot about any history of convulsions. Talk with them about medicines or other ways you can reduce fever from the shot. If there was a problem after receiving the first MMR or separate shots for measles, mumps, or rubella, be sure to tell the doctor or nurse before receiving a second shot of the vaccine. WHAT TO LOOK FOR AND TO DO AFTER THE SHOT Talk with the doctor or nurse who gives the shot about medicines or other ways you can treat fever from the vaceine. This pamphlet lists the problems (on pages 3, 4, 6, and 7) that may occur after receiving MMR or other shots for measles, mumps, or rubella. As with any serious medical problem, if the person has a serious or unusual problem after getting the vaccine, CALL A DOCTOR OR GET THE PERSON TO A DOCTOR PROMPTLY. If you or your child does have a reaction to the vaccine, you can help your doctor by writing down exactly what happened. Use this form or write on a piece of paper exactly what happened, what day it happened, and the time it happened. Type of Vaccine and Date Received: Problems Day and Time Problem Started

#### **HAVE THE PROBLEM REPORTED:**

The Public Health Service is interested in finding out if any serious problems may be related to MMR, measles-rubella, measles, mumps, or rubella vaccines, especially those that occur within 4 weeks after the shot.

If you believe that the person receiving the vaccine had a serious problem or died because of the shot:

Call this number:

And ask the doctor or health department to report the problem on a Vaccine Adverse Event Report form.

If you think the problem was not reported, you should report the problem yourself. You can get the form by ealling this toll-tree number: 1-800-822-7967.

\_\_\_\_\_

#### **GET INFORMATION ABOUT POSSIBLE HELP:**

A U.S. government program provides compensation for some persons injured by vaccines. For more information, call this toll-free number: 1-800-338-2382

OR contact: The U.S. Claims Court, 717 Madison Place, NW, Washington, DC 20005, (202) 633-7257

Important Information About Hepatitis B, Hepatitis B Vaccine, and Hepatitis B Immune Globulin

Editor's Note: This portion of Exhibit 2 was partially illegible as submitted to the Secretary of State's Office for publication. Therefore, this information is not reprinted here. For copies of this information, please contact the Department of Health Services.

Arizona Department of Health Services

#### **INFORMATION AFTER IMMUNIZATIONS**

(Nama)	hac	inet	racaiwad	tha	following	immunization(c)	(data)
(Name)	mas	just	received	tile	Tollowing	illillullization(s)	(date)

Parent or Guardian: Remember to inform your child's School or Child Care Center that this immunization has been received

[] DTP (Diphtheria, Tetanus, Pertussis) [] DT (Diphtheria, Tetanus)

[] Td (Tetanus, Diphtheria-adult).

Ouring the first 2 days following immunization, slight fever, irritability, local redness and/or tenderness at site of injection are common. Give extra fluids. Call your doctor or hospital if your child develops any more serious reactions such as fever over 105° F, abnormal crying for several hours or convulsions. If there is a family history of convulsions in parents or brothers or sisters, give a non-aspirin fever medication when vaccine is received and every 4 to 6 hours for 48-72 hours.

#### [] OPV (Oral Polio Vaccine)

< This vaccine rarely produces side effects. Polio virus is shed in the stool for 6 weeks. Wash your hands carefully after diaper changes or assisting with toileting.</p>

#### IPV (Inactivated Polio Vaccine)

<> No anticipated reaction.

#### MMR (Measles, Mumps, Rubella)

Measles <> A non-contagious rash and/or slight fever may occur 1-2 weeks following immunization. Give extra fluids for fever.

Mumps <> No specific treatment recommended.

Rubella <> Rash, mild swelling of neek glands, joint swelling or aching may occur 1-3 weeks after receiving vaccine. Usually no treatment is recommended. See your doctor if this is severe.

If there is a family history of convulsions in parents or brothers or sisters, consideration should be given to giving a non-aspirin fever medication five days after the vaccine is received and then every 4 to 6 hours for 5 to 7 days.

#### [] Hib (Meningitis) - Haemophilus influenzae b

Some children will get fever, redness, swelling or tenderness at the site of injection. Give extra fluids. Some children will have

fever of 102.2° F or higher.

#### **IMPORTANT:**

- If there is fever over 101° F, follow your doctor's direction for fever medication.
- \*Relieve redness and tenderness at injection site by placing a cold washeloth on the area for 15 minutes every 2-3 hours.
- \*If swelling remains after 24 hours, use a warm washeloth on the area for 15 minutes every 2-3 hours.

**IMMUNIZATION** 

**SCHEDULE** 

2 months DTP, OPV, Hib, 4 months DTP, OPV, Hib, 6 months DTP, Hib, 15 months DTP, OPV, MMR, Hib, 4-6 years DTP, OPV, Every 10 years Td

Schedule for Completion (date doses needed)

<del>Vaccine</del>	1	<del>2n</del>	<del>3r</del>	4t	<del>5t</del>
	st	d	d	h	<del>h</del>
DTP and/or DT/	-	_	-	-	-
<del>Td-</del>					
OPV/IPV	-	-	-	-	-
MMR	-	-	-	-	-
Hib	-	_	-	-	-

If the receiver of the vaccine becomes ill and visits a doctor, hospital or clinic during the 4 weeks after immunization(s), please report it to your County Health Department at:

ADHS/DDP/IMM/107 (Rev. 3/91) \*See reverse side for information on fever.

Temperatures on infants and young children are generally taken with a thermometer, placed under the arm or inserted in the rectum. Temperatures are taken by mouth (oral) only if the child is old enough to keep the thermometer under the tongue with the mouth closed to avoid biting and possibly breaking the thermometer. Ask your doctor or nurse to teach you how to use and read a thermometer.

Fevers are best treated by giving your child more liquids to drink (water, clear juices, such as apple; or soft drinks such as ginger ale, lemon/lime). Lukewarm tub baths or sponge bathing may also help bring the fever down. Fevers can also be treated with aspirin or non-aspirin products.

For fever prevention, a non-aspirin product such as Tylenol, Tempra, Liquiprin, etc. may be given. There are many non-aspirin (Acetaminophen) products available. Your decision to buy it in liquid or tablet form will depend on the age of your child. It is important that you carefully read the instructions included with the product to know how much you should give and how often it should be given. If you have questions ask your doctor or clinic.

A child with a fever lasting longer than 2 days or one which will not go lower than 101° F with treatment needs medical attention. Consult your doctor/or clinic.

### Exhibit 3. Consent For Immunization Repealed NAME:

I have been given a copy and have read or had explained to me the information contained in the Important Information Statements about the following disease(s) and vaccine(s): polio (live and killed), Diphtheria, Tetanus, Pertussis, Measles, Mumps, Rubella singly or in combination, Haemophilus Influenzae type b, and Hepatitis B. I have had a chance to ask questions which were answered to my satisfaction. I believe I understand the benefits and risks

### **Notices of Exempt Rulemaking**

of the vaccine(s) and request that the vaccine(s) indicated on this form be given to me or the person named on this health record for whom I am authorized to make this request. I understand these pamphlets may go home with me.

	DOSE	SIGNATURE OF PERSON TO RECEIVE VACCINE	DATE
	DOSE	OR PERSON AUTHORIZED TO MAKE REQUEST	DAIL
		OK PERSON AUTHORIZED TO MAKE REQUEST	
OPV			
Oral			
IPV			
(IM)			
DTP			
L arm/L leg (IM)			
DT			
L arm/L leg (IM)			
Td			
L arm (IM)			
Hib			
R arm/R leg (IM)			
MMR /			
R arm/SO			
HBV			
R arm (IM)			
Tb Skin Test			

Adapted from the Maricopa County Public Health Services "Consent for Immunization" RECALL 2 mo 6 mo 1 yr 3 OPV, 4 DTP, 1 Hib, 1 MMR

**Exhibit 4. Vaccine Administration Repealed** 

Vaccine	Dose	Route*	Site	Remarks Epinephrine (1:000 must be available at all times)
OPV Oral Polio	2 gtts.	Oral	Mouth	Back of tongue or buccal mucosa Vaccine is clear and pink, to orange.
IPV Inactivated Polio	0.5 ml.	Subcutane- ous	Deltoid	After insertion of needle, aspirate before injecting, to make certain no blood is withdrawn. Vaccine is clear, colorless.
DTP (Diphtheria, Pertussis, Tetanus) to age 7	0.5 ml.	Intramuscu- lar	Infants: Non- walking, Vas- tus Lateralis (mid lateral thigh) anterolateral (Left) Children	Shake well before withdrawing. After withdrawing vaccine into the syringe and before injecting take care not to let the preparation dribble down the needle. To keep a drop from forming at the needle tip, pull back on the syringe plunger slightly, so that a little air
DT (Diphtheria, Tetanus) to age 7	ml.	lar Intramuscu-	walking, Deltoid (left arm)	enters the needle (this causes no harm). These measures reduce the amount of vaccine that is tracked through subcutaneous tissue. Aspirate before injecting vaccine. Vaccine is cloudy white color.
Td (tetanus, diphtheria) age 7 and older	ml.	lar		winte color.
Hib Haemophilus b Conjugate	0.5 ml.	Intramuscu- lar	Vastus Lateralis deltoid (Right leg/arm)	Aspirate before injecting vaccine. Vaccine is clear and colorless.
HBV Hepatitis B	Per mfg. and age	Intramuscu- lar	Vastus Lateralis deltoid (Right leg/arm)	Aspirate before injecting vaccine. Vaccine is clear and colorless.
M, MR, MMR Measles, Mumps, Rubella	0.5 ml.	Subcutane- ous	Outer aspect of upper arm (right arm)	Use only diluent supplied for MMR products. Shake well before withdrawing. Aspirate before injecting vaccine. Vaccine is clear, straw color.

<sup>\*</sup> Needle size for administration:

Subcutaneous: 5/8" 25 gauge

Intramuscular: 1" to 1 1/2" 21 to 23 gauge

#### R9-25-806. Testing of Medical Treatments, Procedures, Medications, and Techniques That

May Be Administered or Performed By an Emergency Medical Technician.

- A. Under A.R.S. § 36-2205, the Department may authorize the testing and evaluation of a medical treatment, procedure, technique, practice, medication, or piece of equipment for possible use by an emergency medical technician or an emergency medical provider.
- **B.** Before authorizing any test and evaluation pursuant to subsection (A), the Department director shall approve the test and evaluation according to subsections (C), (D), (E).
- <u>C.</u> The Department director shall consider approval of a test and evaluation conducted pursuant to subsection (A), only if a written request for testing and evaluation:
  - 1. Is submitted to the Department director from:
    - a. The Department;
    - b. A state agency other than the Department:
    - c. A political subdivision of this state;
    - d. An emergency medical technician:

<sup>\*</sup> For simultaneous administration of HBV and Hib: use right vastus lateralis for both with one inch between sites.

#### **Notices of Exempt Rulemaking**

- e. An emergency medical services provider;
- f. An ambulance service, or
- g. A member of the public; and
- 2. <u>Includes</u>:
  - a. A cover letter, signed and dated by the individual making the request;
  - b. An identification of the person conducting the test and evaluation:
  - c. An identification of the medical treatment, procedure, technique, practice, medication, or piece of equipment to be tested and evaluated;
  - d. An explanation of the reasons for and the benefits of the test and evaluation;
  - e. The scope of the test and evaluation, including the:
    - i. Projected number of individuals, emergency medical technicians, emergency medical services providers, or ambulance services involved; and
    - ii. Proposed length of time required to complete the test and evaluation; and
  - g. The methodology to be used to evaluate the test's and evaluation's findings.
- **<u>D.</u>** The Department director shall approve a test and evaluation if:
  - 1. The test and evaluation does not pose a threat to the public health, safety, or welfare:
  - 2. The test is necessary to evaluate the safest and most current advances in medical treatments, procedures, techniques, practices, medications, or equipment; and
  - 3. The medical treatment, procedure, technique, practice, medication, or piece of equipment being tested and evaluated may:
    - <u>a.</u> Reduce or eliminate the use of outdated or obsolete medical treatments, procedures, techniques, practices, medications, or equipment;
    - b. Improve patient care; or
    - Benefit the public's health, safety, or welfare.
- E. Within 180 days of receiving a written request for testing and evaluation that contains all of the information in subsection (C), the Department director shall send written notification of approval or denial of the test and evaluation to the individual making the request.
- **F.** Upon completion of a test and evaluation authorized by the Department director, the person conducting the test and evaluation shall submit a written report to the Department director that includes:
  - a. An identification of the test and evaluation,
  - b. A detailed evaluation of the test, and
  - c. A recommendation regarding future use of the medical treatment, procedure, technique, practice, medication, or piece of equipment tested and evaluated.